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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	Dosuk D. Lee et al.	Confirmation No.:	2121
Serial No.:	09/284,297	Art Unit:	1615
Date Filed:	July 5, 2000	Examiner:	Neil S. Levy
Customer No.:	21559		
Title:	METHOD OF PREPARING A POORLY CRYSTALLINE CALCIUM PHOSPHATE AND METHODS OF ITS USE		

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APPELLANTS' REPLY BRIEF
SUBMITTED PURSUANT TO 37 C.F.R. § 41.41

In support of Appellants' Notice of Appeal that was filed in connection with the above-captioned application on February 23, 2006, and Appellant's Appeal Brief that was filed on May 17, 2007, and with reference to the final Office Action that was mailed in this application on August 23, 2005, and the Examiner's Answer that was mailed on November 19, 2007, submitted herewith is Appellants' Reply Brief.

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Status of Claims

Claims 1-39, 41, 44-102, 104-110, and 144 are canceled. Claims 40, 42, 43, 103, 111-143, and 145-153 are currently pending and are under appeal.

As indicated by the Examiner in the Examiner's Answer, claims 121-123, 135-137, 146, 147, 149, 150, and 153 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.¹

Claims 40, 42, 43, 103, 111-120, 124-134, 138-143, 145, 148, 151, and 152 continue to be rejected for the reasons given in the final Office action mailed August 23, 2005, and in the Examiner's Answer, and are under appeal.

¹ The Examiner's Answer appears to include a typographical error in the statement relating the status of objected to claims. In particular, the statement indicates that "Claims 12-123...are objected to." Because claims 12-39, 41, 44-102, and 104-110 are cancelled, Appellants believe the Examiner intended to state that "Claims 121-123...are objected to."

Grounds of Rejection to be Reviewed on Appeal

This appeal presents three issues²:

1. Whether the Examiner erred in rejecting claims 43, 127-131, 133, and 134 under 35 U.S.C. § 102(e) for anticipation by U.S. Patent No. 5,962,028 (hereinafter “the ‘028 patent”).
2. Whether the Examiner erred in rejecting claims 42, 43, 126-134, 151, and 152 under 35 U.S.C. § 102(e) for anticipation by U.S. Patent No. 5,782,971 (hereinafter “the ‘971 patent”).
3. Whether the Examiner erred in rejecting claims 40, 43, 103, 111-120, 124-134, 138-143, 145, 148, 151, and 152 under 35 U.S.C. § 103(a) for obviousness over the ‘971 patent in combination with U.S. Patent No. 6,005,162 (hereinafter “the ‘162 patent”).

² The grounds for appeal recited here are modified from those recited in Appellants Brief on Appeal filed on May 17, 2007, owing to the Examiner’s modifications in the Examiner’s Answer mailed on November 19, 2007.

Argument

Rejection of Claims 43, 127-131, 133, and 134 under 35 U.S.C. § 102(e) over the ‘028 Patent

The Examiner maintains the rejection of claims 43, 127-131, 133, and 134 under 35 U.S.C. § 102(e) over the ‘028 patent on two grounds: 1) the ‘028 patent describes a compressed powder object and 2) independent claim 43, and claims dependent therefrom, is open-ended and does not exclude liquid, and thus, the ‘028 patent anticipates claims 43, 127-131, 133, and 134 owing to its disclosure of “mechanically dry...mixed materials...with water” (Examiner’s Answer pp. 4 and 9). With respect to the first ground, the Examiner states:

As to Constantz, ‘028, appellant argues compressed, not defined in the specification is defined in a dictionary. Examiner finds the term can be taken in its broadest meaning; Constantz applies pressure, compression, via syringe, molding, kneading, shaping & forming in addition to the mixing seen as resulting in some degree of compression, although not the specific example as shown in the pellet formation of the instant specification at lines 25-27 on page 61, and of claims 149 and 150. Uniform dispersion of compressed powders is in accord with both the instant claims & with the result of mixing by Constantz – we don’t see a conflict. (Examiner’s Answer, p. 9; bold in original excluded.)

The Examiner even acknowledges that the ‘971 patent does not teach the compression of dry powders (see page 6).

Although Appellants have addressed this ground for the rejection in detail in the Brief on Appeal filed on May 17, 2007 (the “Appeal Brief”), and wish to incorporate those comments by reference herein, Appellants wish to comment specifically on the Examiner’s statement that the ‘028 patent describes “appl[ying] pressure, compression, via syringe, molding, kneading, shaping & forming in addition to the mixing seen as resulting in some degree of compression” (Examiner’s Answer, p. 9). Nowhere does the ‘028 patent describe the application of pressure to, or the molding, kneading, shaping, or forming of, powders of a calcium phosphate to form a

compressed powder object, as is recited in present independent claim 43, and claims dependent therefrom. Instead, the ‘028 patent describes the injection via syringe, molding, kneading, shaping, and forming of a calcium phosphate composition only after a lubricant, such as water, has been added to form a flowable “paste” or moldable “clay-like putty” (see, e.g., col. 6, lines 10-13 and 29-36, and col. 7, lines 44-62, of the ‘028 patent); a flowable paste or moldable putty is not a compressed *powder* object. Prior to the addition of a lubricant, the powder of the ‘028 patent exists solely as a uniform dispersion, not as a compressed powder object (see col. 5, line 66, through col. 6, line 9). The Examiner improperly broadens the term “compression” to encompass a meaning that is contrary to its use in the present claims and specification, even while recognizing that the ‘028 patent does not teach or suggest “compression” as this term is used in the present specification (see Examiner’s Answer page 9; “Constantz applies pressure, compression, via syringe, molding, kneading, shaping & forming in addition to the mixing seen as resulting in some degree of compression, *although not the specific example as shown in the pellet formation of the instant specification at lines 25-27 on page 61, and of claims 149 and 150*”; emphasis added). The Examiner also acknowledges the distinction between Appellants’ compressed powder object and the physical manipulation of pastes and putties described in the ‘971 patent, which discloses no more than that in the ‘028 patent (see Examiner’s Answer, p. 6; “The instant claim 40 compression followed by hydration *is not clearly recited at Constantz*”; emphasis added).

With respect to the second ground on which the present rejection is based, the Examiner states:

Claim 43 requires a shaped compressed powder object comprising powders of Calcium Phosphate (CaP) and material to promote conversion of CaP to poorly crystalline apatitic CaP (PCA). This composition, in comprising guise, does not

exclude liquid, in fact as of instant dependent claim 127.” (Examiner’s Answer, pp. 3-4.)

Notwithstanding the fact that present independent claim 43 includes the transitional term “comprising,” which is an inclusive or open-ended term that does not exclude additional, unrecited elements (see M.P.E.P. § 2111.03), claim 43 cannot be read to exclude the very elements that are actually recited in the claim, to wit, “*dry powders* of a calcium phosphate and a promoter...selected to promote conversion of said calcium phosphate into a strongly bioresorbable, poorly crystalline apatitic calcium phosphate” which are compressed to form the recited compressed powder object (emphasis added). For the reasons discussed above and in the Appeal Brief, the ‘028 patent fails to teach or suggest a compressed powder object, much less a compressed powder object that is subsequently hydrated. Moreover, the recitation, in dependent claim 127, that the compressed powder object “further comprises a hydration medium to hydrate the object,” does not change the fact that the composition of claim 43 is a “compressed powder object...comprising dry powders”; dependent claim 127 only adds a hydration medium to “hydrate the object,” similar to an Alka-Seltzer® in a glass of water. In other words, the hydration medium hydrates the dry powders of the compressed powder object in order to convert the calcium phosphate and promoter into a strongly bioresorbable, poorly crystalline apatitic calcium phosphate. Because the ‘028 patent fails to teach or suggest a compressed powder object, whether dry or present in a hydration medium, Appellants respectfully request that the Board reverse the rejection of claims 43, 127-131, 133, and 134 under 35 U.S.C. § 102(e) over the ‘028 patent.

*Rejection of Claims 42, 43, 126-134, 151, and 152
under 35 U.S.C. § 102(e) over the '971 Patent*

The Examiner also maintains the rejection of claims 42, 43, 126-134, 151, and 152 under 35 U.S.C. § 102(e) over the '971 patent. The Examiner states that “Constantz provides an example of mixing of dry powders, including CaP (considered as the instant supplemental ingredient), the instant promoter Ca carbonate, and amorphous calcium phosphate (ACP), & pressing. No liquid is added, thus claim 43 is anticipated” (Examiner’s Answer, p. 5).

Appellants first address the Examiner’s comments as they apply to claims 43, 126-134, 151, and 152. Appellants have previously explained that the deficiencies of the '971 patent are the same as those of the '028 patent. Thus, Appellants respectfully request that the comments made above with respect to the rejection of claims 43, 127-131, 133, and 134 over the '028 patent be fully applied to the rejection of claims 43, 126-134, 151, and 152 over the '971 patent. Appellants believe that, for the reasons given above and in the Appeal Brief, the '971 patent fails to teach or suggest the compressed powder object of independent claim 43. Moreover, because the '971 patent fails to teach or suggest all of the limitations of present claim 43, dependent claims 126-134, 151, and 152 are also novel and non-obvious. Appellants respectfully request that the Board reverse the rejection of claims 43, 126-134, 151, and 152 under 35 U.S.C. § 102(e) over the '971 patent.

With respect to independent claim 42, the Examiner states that the '971 patent describes the dry mixing of powders of a calcium phosphate, which is considered as “the instant supplemental material,” a calcium carbonate, and an amorphous calcium phosphate (ACP; Examiner’s Answer, p. 5). The Examiner fails, though, to indicate where the '971 patent teaches or suggests a composition having the combination of elements recited in present independent claim 42: a *PCA calcium phosphate* and a calcium phosphate as the supplemental material. The

‘971 patent only describes the combination of amorphous calcium phosphate (ACP) with additional sources of calcium, including calcium phosphates (namely tetracalcium phosphate, tricalcium phosphate, dicalcium phosphate and its dihydrate, and monocalcium phosphate and its monohydrate; see, e.g., col. 4, lines 12-22). Nowhere does the ‘971 patent teach or suggest the combination of a PCA calcium phosphate with a second calcium phosphate. Thus, Appellants respectfully request that the Board reverse the rejection of independent claim 42 under 35 U.S.C. § 102(e) over the ‘971 patent.

Rejection of Claims 40, 43, 103, 111-120, 124-134, 138-143, 145, 148, 151, and 152 under 35 U.S.C. § 103(a) over the ‘971 Patent in view of the ‘162 Patent

The Examiner maintains the rejection of claims 40, 43, 103, 111-120, 124-134, 138-143, 145, 148, 151, and 152 under 35 U.S.C. § 103(a) over the ‘971 patent in combination with the ‘162 patent. The Examiner states:

The instant claim 40 compression followed by hydration is not clearly recited at Constantz, although the reiteration in the patent of dry mixing, with wet ingredients then added, followed by shaping, molding, packing & the like (as at col. 6, lines 35-39) & to filling voids in bones (col. 6, lines 58-62) would make it evident to the artisan that the process of the instant compression. (Examiner’s Answer, p. 6; emphasis added.)

Appellants remain baffled by the Examiner’s maintenance of the rejection of independent claims 40, 43, and 103, and their dependent claims, in view of his acknowledgement in the Examiner’s Answer that the ‘971 patent does not describe the compression of dry powders (see emphasis above). Furthermore, as was discussed in Appellants’ Appeal Brief, the ‘971 and the ‘162 patents clearly describe “calcium phosphate cements” (see Abstract of the ‘971 Patent), not compressed powder objects made by compressing dry powders of a calcium phosphate. The cement compositions described in the ‘971 and ‘162 patents are formed by hydrating uniformly

dispersed powders with a liquid, such as water, to form a paste or putty that eventually sets and hardens after a chemical reaction that incorporates the liquid component into the powders. In contrast, independent claims 40, 43, and 103 recite compressed powder objects having a predetermined shape that are formed by compressing dry powders of a calcium phosphate and a promoter; the compressed powder objects can be subsequently hydrated by, e.g., their placement into a hydration medium or their contact with fluids *in vivo*. Nowhere does either the '971 patent or the '162 patent teach or suggest such a compressed powder object.

The Examiner states that "shaping, molding, packing & the like" (Examiner's Answer, p. 6), as well as kneading, rolling, and packing (Examiner's Answer, p. 8) meets the limitation "compressing" or "compressed" in independent claims 40, 43, and 103. This is simply incorrect. The '971 and the '162 patents only refer to the use of kneading and rolling to "mechanically disperse," not compress, the dry ingredients (see, e.g., col. 6, lines 21-26, of the '971 patent), while the '971 and the '162 patents refer to the use of shaping and packing with respect to paste or putty compositions (i.e., compositions formed by hydrating uniformly dispersed powders with a liquid; see, e.g., col. 6, lines 21-39, of the '971 patent), not the formation of compressed powder objects; the '971 and the '162 patents fail to teach or suggest the shaping and packing of dry powders lacking a fluid (i.e., compression) to form a compressed powder object. The Examiner's characterization of the '971 and the '162 patents to the contrary is simply erroneous.

Finally, the Examiner states that "explicit compressing was evident at col. 8, IIIA. Of the '971 patent" (Examiner's Answer, p. 11). As is discussed in Appellants' Appeal Brief, this portion of the '971 patent refers to the compression testing of hardened cement compositions, which, as is discussed above, are not compressed powder objects. Thus, this portion of the '971 patent is irrelevant to the subject matter of present independent claims 40, 43, and 103, and

claims dependent therefrom. For the reasons given here and in the Appeal Brief, Appellants respectfully request that the Board reverse the rejection of independent claims 40, 43, and 103, and claims dependent therefrom, under 35 U.S.C. § 103(a) over the '971 patent in combination with the '162 patent.

With respect to independent claim 138, which recites a method of preparing a bioceramic implant composition by mixing powders of a calcium phosphate with one of the indicated promoters in a hydrating medium to form a paste and allowing the paste to harden after it has been placed in a mold that approximates a desired shape, the Examiner states that “[i]nstant claim 138 requires introducing the CaP & promoter with lubricant into a mold, not so pointed to by Constantz. However, a prosthetic implant is suggested (col. 6, lines 58-60), thus one would recognize formation of such a product would be done using a mold” (Examiner’s Answer, p. 6). Appellants respectfully disagree.

As was discussed in Appellants’ Appeal Brief, neither the '971 patent nor the '162 patent teaches or suggests the use of a mold to prepare a bioceramic implant having a desired implant shape. The '971 patent only discloses that “[w]here the product is to be introduced in situ, it may be injected into the appropriate site, which may be actively bleeding, using a syringe or catheter, or packed in by other means, as appropriate” (col. 6, lines 35-39). Nowhere does the '971 patent teach or suggest the use a mold to form the cement composition into a desired implant shape; the paragraph referred to by the Examiner does nothing to change this fact because it only suggests how the calcium phosphate cements of the '971 patent can be used, not how they can be formed to achieve that use.

Finally, as is discussed by Appellants in the Appeal Brief, any reference in the '971 and '162 patents to the use of a mold or compression die relates only to the testing of the hardened

calcium phosphate cement compositions to determine their compression strength (see, e.g., col. 8, line 65, through col. 9, line 55, of the '162 patent). Both the '971 and the '162 patents fail to teach or suggest the use of a mold that approximates a desired implant shape to prepare a bioceramic implant composition, as is required by independent claim 138. Thus, for all the reasons given above and in the Appeal Brief, Appellants respectfully request that the Board reverse the rejection of independent claim 138, and claims dependent therefrom, under 35 U.S.C. § 103(a) over the '971 patent in combination with the '162 patent.

CONCLUSION

For all the reasons provided above and in the Appeal Brief filed on May 17, 2007, the real party in interest, Etex Corporation, a small entity, requests that the Board reverse the Examiner's rejections of pending claims 40, 42, 43, 103, 111-120, 124-134, 138-143, 145, 148, 151, and 152.

Appellants submit that the Reply Brief is timely filed as the deadline for filing the brief, January 19, 2008, fell on a Saturday, and Monday, January 21, 2008, was a federal holiday.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully Submitted,

Date: 1-22-08


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